SPECIAL SESSION
ADVANCING AQUACULTURE DRUG APPROVALS BY
STRATEGIC COORDINATED RESEARCH

6TH MEETING OF THE
NATIONAL AQUACULTURE DRUG RESEARCH FORUM
February 10, 2008

Held in conjunction with the Aquaculture American 2008 Conference
Lake Buena Vista, Florida

MISSION STATEMENT

"To advance scientific knowledge and coordinate research activities to expedite the approval of new animal drugs."

The goal of the forum is to develop a strategic plan component to work on issues relative to drug approval research activities, including (1) providing a forum for the exchange of information and mutual education between CVM review teams and representatives from academia, the pharmaceutical industry, aquaculture industry, and other government agencies, (2) establishing a repository of useful information and documents, and (3) to create a mechanism to broadly disseminate information relative to drug approval research activities.

Forum Co-Chairs:	
FDA-OR	Renate Reimschuessel
USDA-ARS	Dave Straus
USDOI-USFWS - AADAP	Jim Bowker
USDOI-USGS – UMESC	Mark Gaikowski

The 6th meeting of the National Aquaculture Drug Research Forum was held in conjunction with Aquaculture America 2008, held in Lake Buena Vista, Florida. The meeting convened at the conclusion the Therapeutic Drug Research Special Session on Sunday, March 10 and was well represented by aquaculture drug researchers, research coordinators, drug and pharmaceutical sponsors, and members of CVM's Aquaculture, Environmental, and Toxicology Teams.

The following agenda items were covered:

1. Under "Discuss general data requirements for microbial food safety (GFI #152) and microbiological ADI (GFI #159) assessment in order to expand the use of approved antimicrobial drugs for aquatic species." Dr. Steve Yan of CVM: Although they all involve antimicrobial drugs and contain microbiological aspects, these guidances serve two different purposes. GFI #159 is a part of the toxicology assessment. It determines whether a microbiological acceptable daily intake (ADI) is needed for an antimicrobial drug for use in aquatic or other food animal species. The guidance outlines a logical, step-by-step approach for sponsors to follow in order to determine if there is any need to determine a microbiological ADI. If the answers to the first three steps are all "yes", then they need to justify whether there is any rationale not to assess either endpoint of concerns, *i.e.*, disruption of the colonization barrier or

change in resistant population among human intestinal flora. He suggested assessing all three initial steps before performing a susceptibility study, which could be more cost-effective. Sponsors may take advantage of drug depletion data in the step-by-step approach, especially in determination of whether a rationale is available that precludes assessing either or both endpoints of concerns. If needed, feel free to contact Dr. A. Haydee Fernandez or Dr. Yan for further needs. GFI #152 is a requirement overseen by a different team, the Microbial Food Safety (MFS) Team. Dr. Jeffrey Gilbert is the team leader. GFI #152 is guidance for a qualitative risk assessment (QRA). However, for most aquatic drugs, it can begin with a *hazard characterization*, an initial step of QRA. With review comments from CVM on the hazard characterization, sponsors usually can receive comments on the submission itself and direction or further requirements for MFS, if any. The QRA is based on OIE's format, containing release, exposure and consequence assessment. They contribute to assigning a risk estimation. Based on the risk estimation, risk management steps are laid out in the guidance for each category of drugs. The most important features for aquatic drugs include extent of use (the number of animals treated and duration), marketing status (VFD versus over-the-counter), etc. (note – minutes provided by Dr. Yan)

2. Mark Gaikowski (USGS UMESC) discussed medicated-feed method transfer study requirements and disseminated a draft medicated-feed method transfer summary paper he developed entitled "Developing Method Transfer Studies for Type C Medicated Feed Assay Methods – A Review". The paper summarizes CVM GFI #136 in relation to the Minor Use, Minor Species regulations. The position paper describes (1) selection of participating laboratories, (2) method demonstration, (3) transfer study feed sample sets, (4) establishing reference concentrations, (5) transfer study methods, and (6) analyzing and reporting results. The position paper is currently being reviewed by select Forum participants and will be available for an "external" review in the near-future.

3. Jim Bowker (USFWS AADAP) discussed establishing a more functional Education and Outreach Team, incorporating an extra-curricular training session to be held in conjunction with the USFWS's annual Drug Approval Coordination Workshop, and identifying potential training topics. At this time, tentative plans are underway to put together a training session led by representatives from CVM's Aquaculture and Biometrics Team to discuss conducting studies to evaluate the effectiveness of parasiticides. Mark Gaikoswki, Dr. Pat Gaunt (Mississippi State University) and Drew Mitchell and Dave Straus (USDA Stuttgart National Aquaculture Research Center) agreed to assist Jim Bowker with either putting this training session together or providing expertise in clinical parasitology. Other outreach venues suggested included hosting Webinars, recording training sessions and disseminating by CD or DVD at a later date, WebEx Seminars, and recording technical presentations with audio that could be viewed by others at a later date. A task force was assembled

4. Mark Gaikowski drafted a Survey of Parasitic-Related Aquatic Animal Health Issues. The intent of the survey is to identify priority aquatic health issues caused by external

and internal fish parasites and to assist various data generating partners in prioritizing their drug approval efforts to control parasites on aquatic organisms. The survey was provided to select fish health biologists and aquaculture drug researchers for their review and comment at the conclusion of the meeting. The following questions/comments were made during the meeting after introduction of the survey:

Question: Jennica Lowell (Kona Blue) – What can fish producers (particularly private producers) do to help
Response: Help identify needs relative to parasites

Comment: Need to get a better idea of the qualifications of fish health professionals that might respond to the survey

Comment: Potential problems with diagnostic capabilities of private producers and their ability to presumptively diagnose fish pathogen

5. Jim provided excerpts from a CVM-accepted protocol that describes in detail methods to count or weigh fish into tanks at the start of a study and count or weigh fish out of test tanks at the end of a study. The AADAP staff had worked with CVM's Aquaculture and Biometrics Team to resolve this issue and how it relates to fish discovered missing at the end of the study. In most cases, missing fish should be considered mortalities and included when calculating total cumulative mortality.

6. Mark and Jim briefly discussed establishing a NADRF product peer-review process. The extent of such a process will be evaluated and instituted in the near-future.

Comment: White papers should be submitted by one Agency (either USFWS, USGS, or USDA)

Comment: CVM can not review white papers and provide guidance. They can, however, offer suggestions

Question: Can Dr. Renate Reimschuessel (CVM's Office of Research) be involved in the peer-review process?

Comment: Dr. R can participate in the review process as a scientist, but not as a CVM reviewer.

7. Fate of the NADRF in the event that the JSA Subcommittee on Drugs, Biologics, and Pesticides no longer functions as it has in the past (i.e., involvement of non-federal representatives). There was group consensus that the NADRF is a functional group made up of federal and non-federal participants that has generated quality products that will help CVM with pre- and post-approval decisions, and that a new home for this Forum should be found in the event that it can no longer be associated with the JSA.

8. The 7th Meeting of the NADRF will be held in conjunction with the 14th Annual Aquaculture Drug Approval Coordination Workshop to be held in Bozeman, MT July 29 – 31, 2008. The Meeting is tentatively scheduled for Friday, August 1, 2008 at 8:30 am.

Meeting Attendees

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